Bayer Environmental Science



Document Processing Desk (REGFEE) Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501

ATTN:

Venus Eagle, PM Team 1

Subject:

Applications for Amendments to Labeling - Addition of Marketing

Claims

Premise 75 Insecticide, EPA Reg.No. 432-1332 Premise 2 Insecticide, EPA Reg. No. 432-1331 Premise 0.5 SC, EPA Reg. No. 432-1362

Premise Pro Insecticide, EPA Reg. No. 432-1449

Dear Ms. Eagle,

Bayer Environmental Science (BES) is submitting documentation for amendment to the labeling of the products referenced above. As discussed recently with Meredith Laws, we are submitting the marketing / advertising claims we would like to use with the Premise range together with a claim substantiation report.

Given that all of these products are essentially identical when applied (ie. the same dilution concentrations of particulate imidacloprid at 0.05 & 0.1%), the single product performance report enclosed is presented to support revisions to all 4 labels. Since our flagship product is Premise 75 Insecticide (EPA Reg. No. 432-1332) we are submitting an R34 amendment application for that product, and the other 3 should be handled as Fast Track "me-too" applications following on (ie. piggybacking), the 432-1332.

11 May 2007

Bayer Environmental Science P.O. Box 12014 2 T.W. Alexander Drive Research Triangle Park, NC 27709

Tel. 919 549-2000 Fax. 919-549-3937

Enclosed for your review are the following;

- 1. Transmittal Document
- 2. Application for Pesticide Amendment (EPA Form 8570-1) for each product
- 3. Five (5) copies of proposed labeling with one copy highlighting the changes proposed (for each product)
- 4. One Compact Disk containing the electronic version of the label (for each product)
- 5. Certification with Respect to Label Integrity (for each product)
- 6. Three (3) copies of "Claim Substantiation Report / Summary of Product Performance Data to support marketing claims on Premise termiticide products", 132 pp. ••
- 7. Three (3) copies of "Significance of Binding on Imidacloprid Degradation in Soils, and Effects of Soil Characteristics on Imidacloprid Adsorption Capacity", 37 pp.

Page 2 of 2

Please contact me directly at my contact information below if you have any questions or require further information.

Best Regards,

Jan Brill

Manager, Registration

Phone; 919/549-2421

Email; jan.brill@bayercropscience.com

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TRANSMITTAL DOCUMENT

Name and Address of Submitter: Bayer Environmental Science, A Business Group of

Bayer CropScience LP 2 TW Alexander Dr.

Research Triangle Park, NC 27709

Regulatory Action in Support of Which This Package is Submitted:

Amendment applications for;

- 1. Premise 75 Insecticide, EPA Reg.No. 432-1332
- 2. Premise 2 Insecticide, EPA Reg. No. 432-1331
- 3. Premise 0.5 SC, EPA Reg. No. 432-1362
- 4. Premise Pro Insecticide, EPA Reg. No. 432-1449

Transmittal Date:

5/11/07

List of Submitted Studies:

11 May 2007

Volume 1 of 3 Consisting of Administrative Materials:

Bayer Environmental Science P.O. Box 12014 2 T.W. Alexander Drive Research Triangle Park, NC 27709

Cover letter explaining the proposed amendment

- Tel. 919 549-2000 Fax. 919-549-3937
- Four (4) EPA Applications for Pesticide Amendment (Form 8570-1), one for each product
- Four (4) copies of proposed labeling for each of the four products
- One (1) copy of proposed labeling for each of the four products with changes highlighted
- 4 Certification with Respect to Label Integrity forms, one for each product
- 4 CDs containing electronic labeling, one for each product

Volume 2 of 3 Consisting of;

Claim Substantiation Report / Summary of Product Perform	nance Data to
support marketing claims on Premise termiticide products,	May 2007,
Guideline No. 810.3600, 132 pages (3 copies)	
	support marketing claims on Premise termiticide products,

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MRID NO	47130201	••••	•
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Volume 3 of 3 Consisting of;

47130202

Significance of Binding on Imidacloprid Degradation in Soils, and Effects of Soil Characteristics on Imidacloprid Adsorption Capacity, Dec. 2002, 37 pages (3 copies)

Company Official: Jan Brill

Signature: Jm Runn

Company Name: Bayer Environmental Science

Company Contact: Jan Brill

Phone: 919-549-2421

